

FREQUENTLY ASKED QUESTIONS ABOUT

Reevaluation of Certain Pesticide Products Containing Pyrethroids, California Notice 2006-13

Department of Pesticide Regulation January 2007

The Department of Pesticide Regulation (DPR) placed certain pesticide products containing pyrethroids into reevaluation on August 31, 2006. The reevaluation is based on monitoring surveys and toxicity studies revealing the widespread presence of pyrethroid residues in the sediment of both agricultural and urban dominated California waterways at levels toxic to *Hyalella azteca* (H. azteca). Scientists conducted sediment bioassays using H. azteca, a resident species found in some Central Valley water bodies. Scientists commonly use H. azteca, an aquatic crustacean, as an indicator of environmental health and water quality in streams, lakes, and other bodies of water. Significant toxicity was observed at numerous sites. There was a high correlation between concentrations of pyrethroids and observed toxicity. Findings further indicate that the unique physical, chemical, and toxicological properties of the pyrethroid class of chemicals contribute to their propensity to accumulate in sediment at toxic levels.



Department of Pesticide Regulation

> Pesticide Registration Branch

1001 I Street P.O. Box 4015 Sacramento, CA 95812 916/445-4400 www.cdpr.ca.gov Pyrethroids are synthetic insecticides. DPR did not include pesticide products containing pyrethrins in this reevaluation because pyrethrins are known to break down rapidly in the environment. Pyrethrins are naturally occurring insecticides found in *Chrysanthemum cinerariaefolium*, a perennial plant with a daisy-like appearance. Additionally, DPR excluded from this reevaluation the following product types: (1) formulated as pressurized liquids, pressurized gasses, or pressurized dusts; (2) where the chemical is impregnated into another material (e.g., ear tags, pet flea collars, ant disks/stakes, but not including fabric); and (3) labeled solely for manufacturing use. DPR excluded these formulation categories because it is unlikely that the pyrethroids in these types of products will move into surface waters or sediments.

For purposes of data requirements, DPR divided pyrethroid chemicals into three groups (see Table 1). The first group (Group I) consists of the first generation or "Type I" photosensitive pyrethroids. Typically, these pyrethroids are used indoors and around residential areas. The second (Group II) and third groups (Group III) consist of the newer second-generation pyrethroids, most of which are "Type II" pyrethroids. The more toxic Group II and Group III pyrethroids are less photosensitive and persist longer in the environment. The two active ingredients (AI's) identified as belonging in Group II have not been detected (or monitored for) in California aquatic sediments. Group III pyrethroids have been detected in aquatic sediments, and both Group II and III pyrethroids are widely used in both agricultural and urban settings.

Table 1. List of active ingredients belonging to the family class of pyrethroids and the data requirement Group they have been identified to.

DPR Chemical Code	Common Name	Group
4038	Bioallethrin	I
2293	D-Allethrin	I
5327	Imiprothrin	I
2093	Phenothrin	I
3985	Prallethrin	Ι
2119	Resmethrin	Ι
1695	Tetramethrin	Ι
2195	Tau-Fluvalinate	II
2329	Tralomethrin	II
3866	(S)-Cypermethrin	III
3956	Beta-Cyfluthrin	III
2300	Bifenthrin	III
2223	Cyfluthrin	III
2171	Cypermethrin	III
3010	Deltamethrin	III
2321	Esfenvalerate	III
2234	Fenpropathrin	III
5877	Gamma-Cyhalothrin	III
2297	Lambda-Cyhalothrin	III
2008	Permethrin	III

What is a reevaluation?

The law, Food and Agricultural Code (FAC) section 12824, requires DPR to continuously evaluate registered pesticide products. DPR does this through its reevaluation program (California Code of Regulations (CCR) sections 6220-6225). Upon receipt of information indicating that use of a pesticide may have caused or is likely to cause an adverse effect to people or the environment, DPR is required to investigate further. The information may come from a number of sources such as data submitted by a registrant, other state or local agency, or the public. If based on that investigation, DPR finds that the pesticide has caused or may have caused a significant adverse effect, reevaluation is triggered. When a pesticide enters reevaluation, DPR reviews existing data and may require registrants to provide additional data. The goal is to determine the extent of the existing and potential hazard and to identify ways to mitigate that hazard.

What are the steps involved in a reevaluation and what are the possible outcomes?

If DPR determines that a pesticide "has caused" or is "likely to cause" a significant adverse effect, reevaluation is initiated. Next, a letter is sent to each registrant with product(s) included in the reevaluation, including details of what is required (i.e., data generation, mitigation, protocol development, etc.) in order to maintain its product's registration in California. Failure to comply with the requirements of DPR's reevaluation may result in cancellation of a registrant's product(s) pursuant to FAC section 12825(h). Simultaneous with the letter to the registrant(s), DPR issues a California Notice to Registrants which lists the affected registrants and products and the basis for the reevaluation. DPR posts these notices on its Web site. The purpose of the notice is to notify the public of the reevaluation's initiation and to announce a 30-day opportunity for interested persons to make comments on the Director's decision. A listing of helpful Web links is located at the end of this document.

Data submitted by registrants are evaluated by the appropriate scientists or specialists in the Pesticide Registration, Medical Toxicology, Worker Health and Safety, Environmental Monitoring, Pest Management and Licensing, and/or Pesticide Enforcement Branches.

DPR concludes reevaluations in several ways. If the data show that use of the pesticide presents no significant adverse effects, DPR concludes the reevaluation without additional mitigation measures. If additional mitigation measures are necessary, DPR may adopt regulations to mitigate the potential adverse effect. Such regulations could make the active ingredient a restricted material. If the active ingredient is already a restricted material, additional permit conditions could be placed on the use of the product in California. In applicable situations, DPR works with registrants and the U.S. Environmental Protection Agency (U.S. EPA) to revise labels to mitigate hazards. If the adverse impact cannot be mitigated, DPR cancels or suspends the registration of the pesticide product.

CCR section 6225 require DPR to prepare a semiannual report describing pesticides evaluated, under reevaluation, or for which factual or scientific information was received,

but no reevaluation was initiated. The semiannual report is located on DPR's Web site under California Notice to Registrants at the address listed at the end of this document.

What is required of a pyrethroid registrant?

DPR mailed out individual letters to registrants identifying the products and active ingredients included in the reevaluation, data requirement group, list of studies and timeframes upon which to submit the information to DPR. DPR required registrants to submit a written proposal describing how it intended to comply with the specified data requirements on or around October 31, 2006. Registrants were required to provide a commitment to conduct the studies or identify who will provide the data on their behalf.

What happens after the registrants agree to generate data to fulfill the requirements of the reevaluation? What is DPR's anticipated schedule and timeframe for this reevaluation?

The studies required for the Type I pyrethroids (Group I) will take six months to two years to complete. Once submitted, DPR will review the studies and determine if these AIs are persistent and mobile enough to require additional studies.

For those registrants with products identified as belonging to the Type II pyrethroids (Groups II and III): within six months, they should submit a sediment analytical method; within one year, submit sediment acute and chronic toxicity; and within two years, submit protocols for off-site movement and soil metabolism studies. Once submitted, DPR will review the data and determine the next steps.

Why is DPR asking for environmental fate studies for those active ingredients in Group I? Isn't there sufficient public literature available?

Environmental fate studies are required for all agricultural use products registered in California. Most active ingredients identified as belonging in Group I are used in homeowner products. Therefore, registrants were not previously required to submit environmental fate data, and public literature is unlikely to satisfy reevaluation data requirements unless it meets specific criteria. For instance, one purpose of the pyrethroid environmental fate data call-in is to acquire similar comparative data for non-agricultural use synthetic pyrethroids to determine their: (1) potential to move off-site from the point of application, and (2) relative persistence in environmental matrices such as soils or sediments. Because these fate data will be used in a relative framework (i.e., in comparisons to other chemicals), it is important that the studies be conducted using similar methodologies and experimental conditions. Consequently, only public literature studies that were conducted using procedures essentially identical to those outlined in the U.S. EPA's Pesticide Assessment Guidelines: Subdivision N, Chemistry: Environmental Fate would be useable. Since U.S. EPA's protocols outline the standard procedures for pesticide registration studies, including method recovery data for the sample matrix, data from the studies can be compared across active ingredients.

Comments on a reevaluation may be submitted to DPR not only during the public comment period but throughout the duration of the reevaluation.

How will DPR use the sediment toxicity data required of Type II pyrethroid registrants?

DPR needs to be able to compare environmental concentrations to toxicity values for sensitive aquatic species. These comparisons can then be used to determine, in consultation with Regional Water Quality Control Boards (Regional Boards), compliance with narrative water quality objectives for toxicity and pesticides. This approach may be used as a stand-alone surveillance monitoring strategy or in conjunction with toxicity testing or bioassessment. Also, a full complement of toxicity values for all pyrethroids is necessary to consistently apply the toxic units approach to samples that contain more than one pyrethroid.

DPR's reevaluation notice states that chronic sediment toxicity studies on *H. azteca* and *C. tentans* can be generated using U.S. EPA's "Methods For Measuring The Toxicity And Bioaccumulation Of Sediment-Associated Contaminants With Freshwater Invertebrates", EPA 600/R-99/064. How will DPR use such data and may an alternative procedure be used?

DPR seeks additional toxicity values for sensitive aquatic species. These values will be compared to environmental concentrations to help determine compliance with water quality objectives. They will also help assure that appropriate data are available when water quality criteria are developed. The U.S. EPA methods referenced in the reevaluation notice are, to our knowledge, the only methods of any standing that may be used to investigate the chronic toxicity of pyrethroids to two key sentinel species: H. azteca and C. tentans. If procedures other than those prescribed in the reevaluation notice can more consistently meet test acceptability criteria, registrants should submit such procedures for review by DPR.

How will DPR update the public on the progress of the reevaluation?

Every six months, DPR issues a progress report on all active reevaluations. The report is titled "Semiannual Report Summarizing the Reevaluation Status of Pesticide Products" and runs January 1st to June 30th and July 1st to December 31st each year. These reports are located on DPR's Web site under California Notice to Registrants.

In addition, DPR staff often provide updates on various reevaluations at the bimonthly Pesticide Registration and Evaluation Committee meetings (PREC). The PREC fulfills a critical interagency consultation role mandated by FAC section 14103 and the certification of the pesticide regulatory program as functionally equivalent under CEQA. It also fosters communication and understanding among DPR and the parties represented on the committee. The PREC provides DPR with advice and guidance on regulatory development and reform initiatives, evolving public policy and program implementation issues, and science issues associated with evaluating and reducing risks from the use of pesticides. More information about the PREC is available on DPR's Web site at the address listed at the end of this document.

DPR staff also provide regular updates at the Urban Pesticide Committee (UPC). The UPC is an interagency and stakeholder forum that meets to share information and coordinate on current issues relating to urban pesticide use and water quality. The UPC meets bimonthly and the Elihu Harris State Office Building in downtown Oakland. Additional information (i.e., agendas and meeting minutes) on the UPC is available on the Urban Pesticide Pollution Prevention Project Web site at the address listed at the end of this document.

How can interested parties be involved in the reevaluation?

The official public comment period on the pyrethroid reevaluation ended October 6, 2006. However, DPR accepts comments on its reevaluations at any time.

Who is the appropriate contact at DPR for additional questions?

If you have any questions regarding the reevaluation process, please contact Ms. Denise Webster by e-mail at <dwebster@cdpr.ca.gov> or by telephone at (916) 324-3522. If you have any questions regarding the required environmental fate, sediment data, and monitoring in areas appropriate to use pattern, please contact Ms. Kaylynn Newhart by e-mail at <knewhart@cdpr.ca.gov> or by telephone at (916) 324-4190. If you have any questions regarding identifying off-site movement, and effectiveness of management practices for off-site movement, please contact Dr. John Sanders by e-mail at <jsanders@cdpr.ca.gov> or by telephone at (916) 324-4155.

Helpful Web links

- Food and Agriculture Code
 http://www.leginfo.ca.gov/cgi-bin/calawquery?codesection=fac&codebody
- California Code of Regulations http://ccr.oal.ca.gov/
- California Notices to Registrants and Semiannual Reports Summarizing the Reevaluation Status of Pesticide Products:

http://www.cdpr.ca.gov/docs/canot/camenu.htm

- List of all current reevaluation notices:
 http://www.cdpr.ca.gov/docs/registration/reevaluation/currentevals.htm
- Pesticide Registration and Evaluation Committee (PREC) http://www.cdpr.ca.gov/docs/prec/precmenu.htm
- Urban Pesticide Pollution Prevention Project http://www.up3project.org/up3 upc.shtml